

31110. Misbranding of Valium. U. S. v. Clematis Laboratories, Inc., and Isadore Chaiklin. Pleas of guilty. Fines, \$20. (F. & D. No. 42587. Sample No. 13911-D.)

The labeling of this product bore false and fraudulent curative and therapeutic claims.

On November 7, 1938, the United States attorney for the District of Massachusetts filed an information against Clematis Laboratories, Inc., Waltham, Mass., and Isadore Chaiklin, alleging shipment by said defendants within the period from on or about November 20 to on or about December 7, 1937, from the State of Massachusetts into the State of Maine of a quantity of Valium which was misbranded.

Analysis showed that the article consisted of sugar-coated tablets of calcium sulfide.

The article was alleged to be misbranded in that certain statements in the labeling regarding its curative and therapeutic effects falsely and fraudulently represented that it was effective to afford relief from the suffering caused by varicose veins, varicose ulcers, or hemorrhoids (piles), and to do so painlessly and safely; effective to improve the circulation of the blood and relieve pressure on the walls of the veins, to correct the conditions that are directly responsible for painful and unsightly varicose veins, to cure obstinate cases of hemorrhoids and that it was effective as an internal medication for varicose veins, varicose ulcers, and hemorrhoids.

On November 27, 1941, pleas of guilty having been entered on behalf of both defendants, they were each fined \$10.

31111. Adulteration and misbranding of Vitatonic. U. S. v. Edward S. Hidden. Tried to the court and jury. Verdict of guilty. Fine, \$600. (F. & D. No. 42694. Sample No. 26243-D.)

This product was labeled to indicate that it contained substantial amounts of vitamins B₁ and D; whereas it contained no demonstrable amounts of such vitamins. Its labeling also bore false and fraudulent curative and therapeutic claims and other misrepresentations.

On September 22, 1939, the United States attorney for the Southern District of New York filed an information against Edward S. Hidden, New York, N. Y., alleging shipment on or about July 20, 1938, from the State of New York into the State of New Jersey of a quantity of Vitatonic which was adulterated and misbranded. The article was labeled in part: (Bottle) "Vitatonic * * * Contains Vitamins The New Day Tonic * * * Prepared by Pharmacists Vitalex Vitamin Laboratories, New York, N. Y."

The article was alleged to be adulterated in that its strength fell below the professed standard or quality under which it was sold, since the statements (bottle label) "Contains Vitamins" and (circular) "Compounded with essential vitamins * * * Vitamin B * * * Vitamin D" represented that it contained vitamins B₁ and D in amounts sufficient to be of therapeutic importance; whereas it contained no demonstrable amounts of vitamin B₁ or of vitamin D.

It was alleged to be misbranded in that the statements (circular) "Vitatonic Vitamin * * * Vitatonic is the ideal food supplement * * * compounded with essential vitamins * * * Vitamin B * * * Vitamin D * * * The marvelous value of vitamins * * * Vitalex Vitamin Laboratories," (bottle) "Vitatonic * * * Contains Vitamins * * * Food Supplement * * * Vitalex Vitamin Laboratories * * * Alcohol 18%," were false and misleading since they represented that it was a food supplement, that it contained vitamin B₁ and vitamin D in amounts sufficient to be of therapeutic importance and that it contained 18 percent of alcohol; whereas it was a drug and not a food, it did not contain vitamin B₁ and vitamin D in amounts sufficient to be of therapeutic importance, since it contained no demonstrable amount of vitamin B₁ or vitamin D and it contained less than 18 percent of alcohol. It was alleged to be misbranded further in that certain statements regarding its therapeutic and curative effects appearing in the accompanying circular falsely and fraudulently represented that it was effective as a body builder for run-down people and weakened bodies; effective as a treatment for disorders of the kidneys, liver and stomach, pyorrhea and caries (decay) of the teeth, hip disease and malformation of the spinal column; effective as a nerve builder; effective to strengthen the stomach and kidneys, to improve health, to relieve pain, to help digestion and assimilation, to clear the complexion, to prevent the condition called polyneuritis, and to tone the system by

coordinating the functions of stomach, liver, kidneys and bowels; and effective as a "vitatonic," i. e., life tonic or vitamin tonic.

On September 5, 1940, the defendant having entered a plea of not guilty, the case came on for trial before the court and a jury. Trial was concluded on September 9, 1940, on which day the jury returned a verdict of guilty on all counts. The court thereupon imposed a fine of \$200 on each of the three counts of the information and also assessed costs.

31112. Adulteration of elixir of phenobarbital and misbranding of Elixir Clorabis. U. S. v. Syracuse Pharmacal Co., Inc. Plea of guilty. Fine, \$200. (F. & D. No. 42681. Sample Nos. 29729-D, 31386-D.)

This case involved elixir of phenobarbital which differed from the standard prescribed by the National Formulary and Elixir Clorabis which contained smaller proportions of ammonium bromide and alcohol than those declared on the label.

On September 11, 1939, the United States attorney for the Northern District of New York filed an information against the Syracuse Pharmacal Co., Inc., New York, N. Y., alleging shipment on or about December 14, 1937, and June 4, 1938, from the State of New York into the State of Pennsylvania of quantities of elixir of phenobarbital which was adulterated and of a quantity of Elixir Clorabis which was misbranded.

The elixir of phenobarbital was alleged to be adulterated in that it was sold under and by a name recognized in the National Formulary but differed from the standard of strength, quality, and purity as determined by the test laid down therein, since each 100 cubic centimeters of the article contained less than 0.38 gram, namely, not more than 0.328 gram of phenobarbital; whereas the National Formulary provides that elixir of phenobarbital shall contain in each 100 cubic centimeters not less than 0.38 gram of phenobarbital, and the standard of strength, quality, and purity of the article was not declared on the label. It was alleged to be adulterated further in that its strength and purity fell below the professed standard and quality under which it was sold, since it was represented to contain in each fluid dram $\frac{1}{4}$ grain of phenobarbital; whereas each fluid dram of the article contained not more than 0.187 grain (less than $\frac{1}{5}$ grain) of phenobarbital.

The Elixir Clorabis was alleged to be misbranded in that the statements, "Each eluid ounce represents: * * * Ammonium Bromide 8 grs." and "Alcohol 12%," borne on the bottle label, were false and misleading since they represented that each fluid ounce of the article contained not less than 8 grains of ammonium bromide and that the article contained not less than 12 percent of alcohol; whereas each fluid ounce contained less than 8 grains of ammonium bromide and the article contained less than 12 percent of alcohol. It was alleged to be misbranded further in that it contained alcohol, and the labels failed to bear a statement of the quantity or proportion of alcohol contained therein since the statement made on the labels was incorrect.

On April 2, 1940, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of \$200.

31113. Misbranding of Blu-V-Spray. U. S. v. Tim Lake Laboratories, Inc. Plea of guilty. Fine, \$10 and costs. (F. & D. No. 42791. Sample No. 37245-D.)

The labeling of this veterinary product bore false and fraudulent representations regarding its curative and therapeutic effectiveness.

On January 12, 1940, the United States attorney for the Southern District of Iowa filed an information against Tim Lake Laboratories, Inc., Des Moines, Iowa, alleging shipment by said company on or about May 12, 1939, from the State of Iowa into the State of Nebraska of quantities of Blu-V-Spray which was misbranded.

Analysis showed that the article consisted essentially of small proportions of volatile oils (including menthol, thymol, eucalyptol, and methyl salicylate) formaldehyde, salicylic acid, and water.

The article was alleged to be misbranded in that certain statements in the labeling regarding its curative and therapeutic effects falsely and fraudulently represented that it was effective as a treatment, remedy, and cure for bronchitis, gapes, colds, pneumonia, diphtheria, intestinal flu, and other infectious poultry ailments of the throat, head, and respiratory organs.

On March 30, 1940, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$10 and costs.